

**REMARKS**

Claims 1 through 3 and 5 through 7 are pending in the application.

Applicants acknowledge with gratitude the Examiner's apparent indication that 5 and 6 are patentable in light of the art of record.

Claim 1 has been amended to emphasize advantageous inventive embodiments in which the thermal treatment is performed at a temperature of approximately 80 °C and the period of time sufficient to remove essentially all of the undesired substances from the carrier material is approximately 0.5 to 6 minutes. Support for this amendment can be found in the Application-as-filed, for example in Claim 2 as-filed.

Claim 1 has also been amended to emphasize the penetration of contaminants into the carrier material. Support for this amendment can be found in the Application-as-filed, for example on Page 3, lines 1 through 3.

Claim 1 has additionally been amended to reflect more conventional process phrasing.

Claim 2 has been canceled, as its subject matter has been incorporated into Claim 1.

Claims 5 and 6 have been amended into independent form.

Applicants respectfully submit that this response does not raise new issues, but merely places the above-referenced application either in condition for allowance, or alternatively, in better form for appeal. Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

Claim Objection

Claims 5 and 6 stand objected to as being in improper dependent form. Claims 5 and 6 have been amended into independent form and further to recite active steps in conformance with conventional United States practice, as kindly suggested by the Examiner.

Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

*The Claimed Invention is Patentable  
in Light of the Art of Record*

Claims 1 through 3 stand rejected over United States Patent No. 5,112,220 ("US 220") to Wimberger et al. Claims 1 and 7 stand rejected as being unpatentable over US 220 and further in view of United States Patent No. 6,153,298 ("US 298") to Joson et al.

It may be useful to briefly consider the invention before addressing the merits of the rejection.

Drugs, confectionary and the like (hereinafter referred to as "consumables") are known for consumption in sheet-like, wafer-like or film-like forms (hereinafter referred to as "film-form"). Various production processes are known for the manufacture of film-form consumables.

In general, film-form consumables are manufactured on fully automated production lines by forming thin sheets of an active-ingredient film on a carrier material. The active-ingredient containing film is then typically peeled off of the carrier material and the separated active-ingredient containing film cut into suitably sized and shaped pieces for administration. The separated carrier material is taken up onto a reel.

Unfortunately, during the film-form production process the active-ingredient (as well as any additional adjuvants or other coating compounds) can penetrate into the carrier material due to diffusion. The carrier material is then contaminated by these substances, up to their respective degree of saturation. Consequently, once the active ingredient containing film has been peeled off the carrier material, the contaminated carrier material can not be used again, since it is loaded to a non-specified degree with diffused active ingredients and the like (hereinafter referred to as "contaminants," as noted above). If the carrier were to be coated a second time, the active ingredients, etc. would penetrate to a different extent, due to the contaminants already present within the carrier. Thus the composition of the resulting active ingredient containing film could change significantly. This is especially unacceptable for the film-form administration of drugs, making any further use of the carrier material almost impossible.

The present invention provides a method for the removal of substances which penetrate into the carrier material during the production process, resulting in the recited treated carrier material that is essentially contaminant-free and which can be used again, for example in the production of further film-form consumables.

Altogether unexpectedly, Applicants have found that such contaminants can be evaporated from carrier materials using simple thermal treatments performed at moderate temperatures and durations, and the evaporated contaminants can then be permanently disposed of by feeding the evaporated contaminants to a thermal after-burner using controlled air circulation, as recited in the claims as-amended.

In particularly advantageous embodiments, the thermal treatment is performed at a temperature of approximately 80 °C for a period of approximately 0.5 to 6 minutes, as recited in Claim 1 as-amended.

The claimed methods provide the added advantage of easy integration into manufacturing processes, especially the manufacturing processes used to produce film-form consumables. The claimed methods thus provide a cost effective process by which to recycle the carrier materials used in film-form consumables, as reflected in Claim 7.

The cited references do not teach or suggest the claimed invention.

US 220 is generally directed to efficient graphic arts dryers that use solvent-laden air as their sole or primary heat source in generating high drying temperatures. (Col. 1, lines 14 – 19 and Col. 2, lines 45 - 51). US 220's driers are intended to dry ink on paper. (Col. 6, lines 1 – 6). US 220 expressly notes dryer temperatures of up to 500 °F (i.e. 260 °C) as suitable. (Col. 6, lines 6 – 7). As correctly noted by the Examiner, US 220 is altogether silent as to treatment duration.

US 220, directed to particular graphic arts dryers, does not teach or suggest methods for removing contaminants from carrier materials, much less carrier materials which have been contaminated by an active-ingredient-containing coating, as recited in the claims.

Nor does US 220, teaching drying temperatures of up to 260 °C, teach or suggest advantageous methods in which essentially all contaminants are removed from a carrier material using a thermal treatment performed at a temperature of approximately 80 °C, as recited in Claim 1 as-amended. US 220 instead teaches away from such moderate temperatures by expressly noting its use of high drying temperatures. Thus there has been no motivation for US 220 to have selected the recited moderate temperature, which Applicants have found sufficient for removing contaminants from a carrier material. Applicants further respectfully submit that the recited 80 °C does not "correspond" to 93 °C as urged within the outstanding Office Action on Page 4.

And US 220, altogether silent as to dryer dwell time, most certainly does not teach or suggest advantageous methods in which the thermal treatment is performed for a period of time of up to 6 minutes, as further recited in Claim 1 as-amended. Nor would there have been any motivation for US 220 to have determined such dwell time, as US 220 does not recognize thermal treatment, much less treatment dwell time, as a result effective variable in removing contaminants from a carrier material.

US 220, altogether silent as to recycling, can not teach or suggest the advantageous inventive methods further comprising optionally cooling the treated carrier and subsequently coating the treated (and optionally cooled) carrier, as recited in Claim 7.

Applicants further respectfully make of record that the urgings of the Office Action on Page 4 that the solvent drying of US 220 can be considered “peeling” are incorrect. Applicants respectfully submit that the term “peeling” refers to the cohesive failure of two solids, such as the cohesive failure between the recited active-ingredient-containing film and the carrier material.

Claims 1 and 7 are likewise patentable in light of US 220 in view of US 298.

US 298 is primarily directed to thermal laminating film including a laminating layer containing vinyl acetate and anti-blocking agents. (Col. 2, lines 47 – 54). The thermal laminating layer can be applied by extrusion coating. (Col. 3, lines 12 – 15). The thermal laminating film is subsequently adhered to a printed surface, particularly surfaces printed with glycol-based inks, via its laminating layer. (Col. 3, lines 30 – 35 and 60 - 64). A “major” advantage of the laminating film is that it melts at 175 °F (i.e. 79 °C). (Col. 7, lines 21 – 23).

There would have been no motivation to have combined US 220 and US 298. US 220 is directed to a particular graphic arts dryer that uses recovered solvent to produce heat. US 298 is directed to thermal lamination films providing adhesion to surfaces printed with glycol-based inks. These are altogether different fields of endeavor and problems solved, to say the least.

However, even if Applicants had combined US 220 and US 298 (which they did not), the claimed invention would not have resulted.

The combination, respectively directed to graphic arts dryers and laminating films, does not teach or suggest methods for removing contaminants which have penetrated carrier materials, much less carrier materials which have been contaminated by an active-ingredient-containing coating, as recited in the claims.

Nor does the combination teach or suggest such advantageous methods in which contaminants are removed from carrier materials using a thermal treatment performed at a temperature of approximately 80 °C, as recited in Claim 1 as-amended. US 298 instead teaches away from such a temperature for decontamination, as it would instead induce melting within its films.

And the combination most certainly does not teach or suggest such advantageous methods in which contaminants are removed from carrier materials using a thermal treatment having a dwell time of up to 6 minutes, as further recited in Claim 1 as-amended.

The combination, both silent as to recycling, likewise can not teach or suggest the advantageous inventive methods further comprising optionally cooling the treated carrier and subsequently coating the treated (and optionally cooled) carrier, as recited in Claim 7. In contrast to the urgings of the Office Action on Page 5, US 298 does not teach or suggest re-use, but instead merely teaches a lamination film applied to printed surface matter. Applicants respectfully submit that the recited carrier material is not intended to become a part of the final product, as is the case in the printed paper of US 298. Instead, the purpose of “carrier material” is an intermediate support. The present invention provides an efficient method by which such carrier materials can be recycled, as reflected in Claim 7.

Priority

As correctly noted by the Examiner, the present invention claims priority to United States Provisional Application No. 60/349,782, whose pendency was subsequently secured through the filing of International Application No. PCT/EP03/00252. A specific reference to the provisional application and international filing has been inserted into the Specification, in conformance with 35 USC 119(e)(1). Applicants' Representative regrets any inconvenience this oversight may have caused.

**CONCLUSION**

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 through 3 and 5 through 7 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that extensions of time or fees are required, beyond those which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time and/or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required is hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,



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Page: 13

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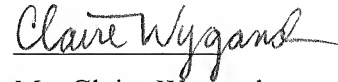
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